

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA**

Alexandria Division

UNITED STATES OF AMERICA

v.

**RIVKA RABI,
a/k/a "Becky Ross,"**

Defendant

Criminal No. 1:15-cr- 126

Hon. Anthony J. Trenga

STATEMENT OF FACTS

The United States and the defendant, RIVKA RABI, agree that the following facts are true and correct, and that had this matter proceeded to trial, the United States would have proven them beyond a reasonable doubt with admissible and credible evidence:

1. Beginning in at least October 2012, and continuing until December 2014, in the Eastern District of Virginia and elsewhere, defendant RIVKA RABI, together with co-conspirators including TC MEDICAL GROUP, SB MEDICAL INC., DAVID E. BURKE, a/k/a "David Johnson," TZVI LEXIER, HANOCH DAVID STEIN, a/k/a "Albert Simmins," ASAF AKIVA IBRAHIMIAN, a/k/a "Adam Darius," and REUVEN MIRLIS, a/k/a "Daniel Mirl," and others, and with intent to defraud and mislead, engaged in a conspiracy to smuggle into and distribute within the United States, including within the Eastern District of Virginia, misbranded prescription drugs and devices.

2. Specifically, members of the conspiracy did knowingly and intentionally combine, conspire, confederate, and agree, with each other and with other persons, to: (a) defraud the United States and its agencies by: impeding, impairing, and defeating the lawful functions of the Food and Drug Administration ("FDA") to protect the health and safety of the

public by ensuring that prescription drugs and devices distributed in the United States were safe and effective from the time of manufacturing to the delivery to the entity that sold or dispensed the product to the ultimate consumer or patient; and impeding, impairing, and defeating the lawful functions of Customs and Border Protection ("CBP") and Immigration and Customs Enforcement—Homeland Security Investigations ("ICE-HSI") to protect the public health and safety by governing the importation into the United States of goods and merchandise, including drugs and devices, through deceitful and dishonest means; (b) fraudulently and knowingly import and bring into the United States merchandise contrary to law, and receive, conceal, buy, sell, or in any manner facilitate the transportation, concealment, or sale of such merchandise after importation, knowing the same to have been imported or brought into the United States contrary to law; (c) introduce into interstate commerce misbranded prescription drugs and devices; and (d) knowingly engage in the wholesale distribution in interstate commerce of prescription drugs in the United States, including to the Commonwealth of Virginia without being licensed to do so.

3. The misbranded and non-FDA approved prescription drugs and devices smuggled and sold by members of the conspiracy included orthopedic injections, rheumatology infusions, cosmetic devices, optomology products, and oncology drugs, which were often subject to stringent storage and handling requirements (such as cold-chain products required to be kept at a consistently low temperature for their safe use), and FDA "black box warnings" which is the strongest warning the FDA requires. The FDA requires "black box warnings" when a drug carries a significant risk of serious or life-threatening adverse effects.

4. The prescription drugs and devices smuggled and distributed by members of the conspiracy were misbranded because they failed to bear adequate directions for use in that they, among other things, (a) were not in the possession of a person, or his agents or employees, who

was regularly and lawfully engaged in the storage or wholesale distribution of prescription drugs or devices; (b) failed to bear a label that contained the required language limiting their use to prescription only and for prescription drugs; (c) failed to bear the FDA-approved labeling and/or at any time before dispensing its label failed to bear, at a minimum, the "Rx only" symbol. The drugs and devices were also misbranded in some cases because the required labeling failed to bear information required under the FDCA in the English language. 21 U.S.C. § 352(f)(1).

5. In addition, neither defendant RIVKA RABI nor any of her co-conspirators were licensed wholesale distributors permitted to sell prescription drugs within the United States and in the Commonwealth of Virginia, and so were not regularly and lawfully engaged in the storage or wholesale distribution of prescription drugs or devices in the United States. Neither RABI nor any of her co-conspirators adhered to appropriate storage and handling, record-keeping, and reporting requirements as would be required of lawful and licensed wholesalers in the United States. In particular:

a. Facilities used by members of the conspiracy for the storage and handling of prescription drugs and devices consisted of unregistered commercial mailboxes at United Parcel Service ("UPS") and other commercial vendors, residential backyards and porches, basement rooms, garages, kitchen fridges and freezers, and personal residences which did not have adequate lighting, ventilation, temperature, humidity, and security as required for the safe handling and storage of prescription drugs and devices. Members of the conspiracy—who did not have any formal training or experience in handling prescription drugs and devices—did not properly quarantine damaged, deteriorated, misbranded, or adulterated prescription drugs and in some cases caused them to be shipped to United States doctors and medical practices.

b. Shipping methods used by members of the conspiracy were designed to evade law enforcement detection, and so often took weeks to arrive in the United States from abroad. Instead of using dry ice or other means of appropriately packing prescription drugs and devices and shipping them by overnight mail, members of the conspiracy often used ice packs and cooling packs, Styrofoam boxes, and other picnic cold packs from Walmart or other stores for shipment over longer periods of time, and often failed to keep cold chain prescription drugs at the required temperatures altogether. As a result, certain FDA-regulated products required to be kept at low and specific temperatures routinely arrived warm, wet, or otherwise damaged.

c. Members of the conspiracy, not being regularly and lawfully engaged in the storage or wholesale distribution of prescription drugs or devices in the United States, did not keep the required records and reports as required of lawful and licensed wholesalers in the United States.

6. TC MEDICAL GROUP and SB MEDICAL INC., under the leadership of DAVID E. BURKE and TZVI LEXIER, and others, caused misbranded and non-FDA approved prescription drugs and devices to be smuggled into the United States and distributed as follows:

a. Beginning in or around April 2011, members of the conspiracy purchased from co-conspiring foreign suppliers prescription drugs and devices manufactured and labeled for use in foreign countries, including the Republic of Turkey, Canada, France, Italy, the United Kingdom, and other countries, and caused them to be shipped into the United States. These prescription drugs and devices were forwarded to the United States through the United Kingdom to doctors and medical practices in the United States, or alternatively to locations including the personal residences and mailboxes of co-conspiring individual drop shippers in the United States.

b. Drop shippers in the United States regularly received packages of prescription drugs and devices from abroad, removed labels and other indicia showing that they had been imported from abroad, repacked the orders, and re-shipped them to doctors and medical practices throughout the United States, including to the Eastern District of Virginia, to give the false impression that the drugs were being distributed domestically and legally.

c. To impede, impair, and defeat the lawful functions of the FDA, CBP, and ICE-HSI, members of the conspiracy engaged in deceitful and dishonest means, including: (i) breaking up large shipments of prescription drugs and devices into smaller separate packages to be sent into the United States to multiple locations, under multiple names, over multiple days, to be consolidated upon arrival after evading border detection; (ii) shipping packages via Royal Mail and Parcelforce Worldwide, which—because they were United Kingdom-based services—allowed packages to be delivered through the United States Postal Service with less scrutiny than would be applied to packages arriving from other countries; (iii) including on customs forms misleading statements about the package contents and value, and addressing packages to co-conspirators under false names and/or titles; (iv) frequently mishandling prescription drugs subject to strict temperature requirements by failing to keep them at a consistent temperature during shipping and storage as required for the drug's safe and effective use; and (v) failing to keep and provide the appropriate pedigree records to prove or track the proper shipping, storage, and transaction history of prescription drugs through the supply chain.

7. Defendant RIVKA RABI served as a New Jersey-based drop shipper for the SB MEDICAL INC. organization. In that role, she opened various commercial mailboxes to receive misbranded prescription drugs and devices from abroad which had arrived under false names including “Dr. Rivka Rabi,” “Meghal Parikh,” “Peter Bogdan,” “Mike Ross,” and “Becky Ross.”

RABI repacked and reshipped non-FDA approved prescription drugs and devices, including to doctors and clinics, and to HANOCH DAVID STEIN, a/k/a "Albert Simmins." Specifically, between approximately October 2012 and approximately December 23, 2014, RABI received approximately \$54,821.15 as payments for receipt and distribution of misbranded and non-FDA approved drugs and devices in the United States, including into the Eastern District of Virginia, for the TC MEDICAL GROUP and SB MEDICAL INC. organization. From approximately April 2011 through December 3, 2014, TC MEDICAL GROUP and SB MEDICAL INC., under the leadership of TZVI LEXIER and DAVID E. BURKE, and together with HANOCH DAVID STEIN, caused to be illegally imported and distributed misbranded prescription drugs and devices within the United States and the Eastern District of Virginia, misbranded and non-FDA approved prescription drugs and devices amounting to at least \$18,494,285 in gross proceeds.

8. In addition, members of the conspiracy including defendant RIVKA RABI using the email address jerseywarehouse123@gmail.com regularly communicated with each other via email about the foreign acquisition, importation and sale of prescription drugs and devices in the United States which were misbranded and illegal to import into the United States, and about the transfer of proceeds from the United States back to Canada. For example:

a. On or about December 19, 2012, a co-conspirator emailed to defendant RABI: "when you receive the package it will come from a Canadian warehouse so any stickers or anything that says CANADA on it needs to be removed..." Defendant RABI responded: "Yes I know I will take care of it."

b. On or about May 20, 2013, a co-conspirator emailed defendant RABI: "If I was shipping this medication from the US I would not put my real return address and I

definitely would not leave my number. You obviously know that there is a Shady/Grey aspect in what we are doing. You need to protect yourself for your sake and for ours.”

c. On or about May 21, 2013, a co-conspirator emailed defendant RABl: “I would rather you use a different address for the Mabthera orders, I included below an address and a phone number that is not associated with us, please don’t ask any questions about it ;o)” Defendant RABl responded: “Um ok thanks.”

d. On or about February 19, 2014, co-conspirator DAVID E. BURKE emailed defendant RABl to stop sending Botox, a cold-chain product, with ice packs to Baltimore, where drop shipper co-conspirator HANOCH DAVID STEIN was located.

9. The statement of facts includes those facts necessary to support the defendant’s guilty plea. It does not include each and every fact known to the defendant or to the government and it is not intended to be a full enumeration of all of the facts surrounding the defendant’s case.

10. The actions of the defendant, as recounted above, were in all respects knowing, voluntary, and intentional, and were not committed by mistake, accident or other innocent reason.

11. The defendant waives any rights under Fed. R. Crim. P. 11(f), Fed. R. Evid. 410, the United States Constitution, and any federal statute or rule in objecting to the admissibility of the Statement of Facts in any such proceeding.

Dana J. Boente
United States Attorney

By: 

Alexander T.H. Nguyen
Kellen S. Dwyer
Jay V. Prabhu
Assistant United States Attorneys

Defendant's Signature: After consulting with my attorney, I hereby stipulate that the above Statement of Facts is true and accurate and that had the matter proceeded to trial, the United States would have proved the same beyond a reasonable doubt.


Date: 4/29/15, 2015



Rivka Rabi
Defendant

Defense Counsel Signature: I am Rivka Rabi's attorney. I have carefully reviewed the above Statement of Facts with her. To my knowledge, his decision to stipulate to these facts is an informed and voluntary one.

Date: 4/29/15, 2015



Robert P. Trout, Esq.
Jesse Winograd, Esq.
Counsel for the Defendant